A study on the influence of dynamic light on sleep an circadian rhythm, in long-stay patients on a haematology ward.

Gepubliceerd: 28-12-2011 Laatst bijgewerkt: 13-12-2022

Artificial dynamic lightening can positively influence the sleep/wake cycle and reduce the disturbance of the circadian rhythm due to hospitalization.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21353

Bron
NTR

Verkorte titel
Dynamic light study

Aandoening

Intensive chemotherapy, intensieve chemotherapie, AML, ALL, Burkitt lymphoma, Burkitt lymfoom, mantle cell lymphoma, mantelcellymfoom, multiple myeloma, multipel myeloom

Ondersteuning

Primaire sponsor: Erasmus Medical Center
TNO
Overige ondersteuning: Erasmus Medical Center
TNO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference in wakefullness during the time presumed sleeping between both groups.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

Artificial dynamic lightening can positively influence the sleep/wake cycle and reduce the disturbance of the circadian rhythm due to hospitalization.

Onderzoeksopzet

Enrolment (demographic data, medical diagnosis, medication, sleep pattern by Munich Chronotype Questionaire, global clinical impression by staff).

During study:

1. Continuous:

Actigraphy by actiwatch, environmental parameters ie vertical and horizontal illuminance levels (due to daylight and/or artificial light), use of sunscreens and/or curtains, use and adjustment by patients/staff of all lighting systems in the room, room temperature, room humidity, position patient (bed or chair), outdoor vertical and horizontal illuminance levels;

2. Once daily:

Heart rate, blood pressure, temperature, quality of sleep (Groninger Sleep Quality Scale);

3. Two times per week:

Pain scored by numeric rating scale (NRS);

4. Weekly:

Hospital anxiety depression scale (HADS), delirium (as weekly revised by a psychiatrist), complications (as noted in the decursus), use of benzodiazepines, antipsychotics, antidepressants, corticosteroids, other medication, WHO performance score, frequency and duration of swith off the study light due to medical reasons or on patients request;

5. Once during admission:

Evaluation of lighting system itself by patients;

6. Periodical:

Noise, ventilation, air flow;

7. At the end of the study:

Global clinical impression by staff, length of stay;

8. In case of early cessation of patient participation:

Reason of cessation;

9. At the end of the entire study period:

Evaluation of lighting system by staff.

Onderzoeksproduct en/of interventie

On the haematology ward of the hospital, 9 single-bed rooms will be equipped with dynamic light as well as standard light. The design of the study is a randomized controlled trial. Patients will be randomized to dynamic light or standard light for their entire stay. If during a subsequent stay (ie second episode) patients participate again, they will be switched to the opposite condition.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patient at least 18 yrs old;

2. Admitted to the haematology dept in a private patient room equipped with dynamic light as well as standard light;

3. Written informed consent;

4. Expected length of stay approx 3 weeks with room arrest;

5. Patients requiring intensive chemotherapy, due to AML, ALL, Burkitt lymphoma, mantle cell lymphoma, and multiple myeloma.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Active depression;

2. Visual handicapped due to ocular pathologies like macula degeneration, severe cataract or severe diabetic retinopathy;

3. Sleep apnoe syndrome;

4. Extreme light sensitivity;

5. Insufficient fluency in Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	17-01-2012
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3069
NTR-old	NTR3217
Ander register	METC Erasmusmc : 2011-174

Resultaten

Samenvatting resultaten
N/A